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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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LUKTON, DAVID

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1653

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/909,733 Examiner David Lukton	Applicant(s) MARTIS ET AL.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 May 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-5, 7, 8 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 32-34 is/are allowed.
- 6) Claim(s) 2-5, 7, 8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) Interview Summary (PTO-413) Paper No(s) _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

Pursuant to the directives of paper No. 13 (filed 5/9/03), claim 6 has been cancelled, and 34 has added. Claims 2-5, 7, 8, 32, 33, 34 are now pending.

Applicants' arguments filed 5/9/03 have been considered and found not persuasive.

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The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 2, 4, 5, 7, 8 are rejected under 35 U.S.C. §103 as being unpatentable over Okamoto (USP 4,880,629) in view of Klein USP (5,039,609).

As indicated previously, Okamoto discloses (e.g., col 12, lines 66-67) a peritoneal dialysis solution in which the glucose is present to the extent of 0.005 - 78 g/liter, and the pH is 5.5-6.5; Klein teaches (e.g., col 4, line 21+) compositions comprising peptides for peritoneal

dialysis. In addition, Klein teaches (col 12, line 40+) that the peptides can be "combined with any osmotically balanced aqueous solution [that is] appropriate...".

In the response filed 5/9/03, it is argued that if two compositions are known (separately) in the prior art, applying the phrase "designed to be mixed" to a description of the compositions confers novelty to those two compositions, even if those two compositions are contained in separate vessels. It is also argued that such an "intended use" qualifier confers novelty to the compositions as a matter of law. With regard to this latter point, no court case (or other authority) has been cited (in the response filed 5/9/03) in support of this proposition, and none is evident. It is also argued (response, 5/9/03) that on page 8 of the specification, there is an assertion that the claimed invention provides "balanced supplementation of polypeptides and glucose through a dialysis solution to improve the nutritional status of the renal patient". First, this is only an assertion, and no argument has been made in the response (filed 5/9/03) that evidence exists which supports the assertion that the nutritional status of renal patients will be improved. In addition, the claims are drawn to two separate, independent solutions which are not in fact mixed in the form that they are in as claimed. There is no requirement (in any of the rejected claims) that any glucose exist in the same solution with a peptide, or *vice versa*. Thus, none of the rejected claims is drawn to a solution in which a "balanced supplementation" is actually required.

Next, it is argued that Klein is deficient in that it fails to suggest combining peptides and glucose in the same solution. As disclosed at col 12, line 40+ the peptides can be "combined with any osmotically balanced aqueous solution [that is] appropriate...". In this passage, dextrose is even mentioned (col 12, line 53+). At least as important is the fact that none of the rejected claims requires that glucose and peptides be present in the same solution. The claims encompass the possibility of having one bag containing a solution that contains peptides (but no glucose) and a second bag which contains a solution that contains glucose (but no peptides). These two bags could be separated by a distance of several yards, and present in e.g., a hospital supply room. Or the two bags could even be separated by a distance of several hundred miles. A company that is located in one city could be the supplier of the glucose solution, and a company located in another city could be the supplier of the peptide solution. A medical practitioner who fully intended to combine the two solutions would then place an order for the solutions from each of the two companies. Thus, a bag containing glucose could be 1000 miles removed from a bag containing peptides, and yet the characterization "intended to be mixed" would be accurate in that situation. At the same time, however, another medical practitioner might order the solutions from the two different companies, and intend not to mix them. Thus, all that the rejected claims require (claims 2, 4, 5, 7, 8) is that a solution containing glucose exists in a given place, and that a solution containing peptides exists in another place. The physical

state of the two solutions is not changed by the intent of the user. Accordingly, the analysis of Klein and Okamoto (response, 5/9/03) is misplaced. The analysis begins with the premise that the claims require the peptides and the glucose to be present in the same solution, and then proceeds to argue that the motivation to prepare a single solution containing both glucose and peptides is lacking. Accordingly, even if it is true that motivation to combine glucose and peptides in a single solution is lacking, the point is moot. This is because the rejected claims (claims 2, 4, 5, 7, 8) do not require the glucose and peptides to be combined in a single solution. The rejection is maintained.

*

Claim 3 is rejected under 35 U.S.C. §103 as being unpatentable over Okamoto (USP 4,880,629) in view of Klein USP (5,039,609).

The teachings of the references were indicated previously. Claim 3 is now discussed separately from the other claims (claims 2, 4, 5, 7, 8) that have been rejected over Okamoto in view of Klein. Claim 3 differs from all of claims 2, 4, 5, 7, 8 in that claim 3 requires the glucose and the peptides to be present in two separate chambers of a single container, whereas the other claims (claims 2, 4, 5, 7, 8) permit the glucose solution to be located in a place which is separate and distinct from where the peptide solution is located. One interpretation of the phrase "two separate chambers of a single container" is that bags of glucose-containing solution are shipped in the same box with bags of peptide containing

solution. That is, if a single order for glucose solutions and peptide solutions were filled by shipping the respective bags together in the same box, the requirements of claim 3 would be met. For this embodiment, the "single container" would be the box, and the "separate chambers" would be the sterile bags containing the solutions. According to this interpretation, all of the arguments set forth in the response filed 5/9/03 are rendered moot, since all of the arguments are based on the invalid premise that the claims require the practitioner to gain possession of a single solution that contains both peptides and glucose.

Claim 3 can also be interpreted to mean that the respective solutions are present in a single container that is designed to hold two different solutions. For this interpretation, there are at least three possibilities with respect to the intent of the practitioner of the invention:

- (a) the two solutions (peptide and glucose) are combined before administering to the patient,
- (b) the two solutions are never combined directly, but are administered simultaneously to the patient, and
- (c) the two solutions are never combined directly, but are administered sequentially to the patient.

The response filed 5/9/03 focuses on the first of these three possibilities. As indicated above, it is argued (response filed 5/9/03) that if two compositions are known (separately) in the prior art, applying the phrase "designed to be mixed" to a description of the compositions confers novelty to those two compositions.

However, the examiner maintains that applying this phrase to a description does not change the physical state of those solutions, and so the solutions are indistinguishable from solutions

to which the phrase at issue has not been applied.

Next, it is argued that Klein does not form the basis for a proper §102 rejection.

However, there has been no assertion by the examiner that Klein could be used in this way.

Instead, the examiner has argued that the claimed solutions are obvious when the teachings of Okamoto are taken in conjunction with those of Klein. In the response (filed 5/9/03), the existence of US Patent 4,880,629 (Okamoto) is acknowledged, and the disclosure therein is characterized as follows: "Okamoto merely relates to dialytic solutions that contain glycerol and monosaccharides as osmotic pressure regulating agents for regulating the osmotic pressure necessary for removal of water". First, the sole purpose of the solutions disclosed in Okamoto is that of peritoneal dialysis, which is identical to the intended use recited in the instant claims. Second, a preferred embodiment in Okamoto is a solution which contains glucose (see, e.g., col 12, line 48+). It is true that the presence of glycerol is also recommended by Okamoto, but the instant claims do not exclude glycerol. The so-called "first part" recited in instant claim 2 (which claim 3 is subgeneric to) "comprises" glucose, and as such can contain glycerol in addition to the glucose. Accordingly, the peritoneal dialysis solution of Okamoto is not distinguished from the so-called "first part" recited in instant claim 2. Claim 3 does not actually require that the glucose and the peptides be combined into a single solution. But combining the glucose and the peptides into a single solution is one of the embodiments that would be encompassed by

claim 3. For this embodiment, it would have been obvious to one of ordinary skill to combine the peptide solution of Klein with the glucose solution of Okamoto for additive effects. That is, the benefits of the glucose and of the peptides (separately) would be realized, while at the same time minimizing the disadvantage of each solution. For example, disadvantages of glucose are discussed in Klein (col 2, line 37+). Thus, by combining glucose and peptides into a single solution, a lower concentration of the glucose and of the peptides can be used, than would be the case if the medical practitioner had to choose between administering glucose (only) and peptides (only). Thus, the possibility of uremia could be minimized, and the caloric intake of the patient could also be minimized. Further, as indicated above, claim 3 would also encompass the possibility of administering the glucose and the peptides *sequentially*. The reasons for doing this would be similar to the reasons for combining the peptides and the glucose into a single solution, i.e., minimizing the adverse effects of either agent that might be realized if administered alone. Thus, claim 3 does not actually require that the glucose and the peptides be combined. But motivation to combine the two solutions, or to use them sequentially does exist, as indicated above. Accordingly, the rejection is maintained.

*

Claims 2-3 are rejected under 35 U.S.C. §103 as being unpatentable over Okamoto (USP 4,880,629) in view of Klein USP (5,039,609), further in view of either of the following: (a)

Loretti (USP 4,997,083) or (b) Larkin (USP 4,608,043).

As indicated previously, Okamoto discloses a peritoneal dialysis solution comprising glucose, and Klein teaches compositions comprising peptides for peritoneal dialysis. Loretti and Larkin both disclose sterile containers which comprise two different chambers for mixing solutions. Loretti also suggests (col 1, lines 14-24) that one compartment could house glucose, and the other amino acids.

In the response filed 5/9/03, no specific argument has been presented as why this ground of rejection might not be justified. It appears that the traversal of Okamoto in view of Klein (without the tertiary references) is intended to apply here as well. In response, the examiner's arguments with respect to the traversal of Okamoto in view of Klein apply here as well.

The rejection is maintained.

*

Claims 2-5, 7, 8 are rejected under 35 U.S.C. §103 as being unpatentable over Klein USP (5,039,609) in view of Faict (USP 5092838)

The teachings of Klein were indicated previously. In addition, Klein discloses (col 3, line 64+) that peptides provide an advantage over amino acids. Faict discloses (col 5, line 15-14) a two part dialysis mixture containing glucose in one part, and histidine, or oligomers thereof, in another.

In the response filed 5/9/03, no specific traversal is offered with respect to this ground of rejection. It is assumed that applicants intend for the arguments presented above in the traversal of the §103 rejection over Okamoto in view of Klein to be applied here as well.

In response, the examiner does the same.

*

Claims 2-3 are rejected under 35 U.S.C. §103 as being unpatentable over Klein USP (5,039,609) in view of Faict (USP 5092838) further in view of either of the following: (a) Loretti (USP 4,997,083) or (b) Larkin (USP 4,608,043)

The teachings of Faict are indicated above; the teachings of Klein were indicated previously. As indicated above, Loretti and Larkin both disclose sterile containers which comprise two different chambers for mixing solutions. Loretti also suggests (col 1, lines 14-24) that one compartment house glucose, and the other amino acids. Neither of Loretti or Larkin disclose the specific solutions recited in instant claim 2.

In the response filed 5/9/03, no specific traversal is offered with respect to this ground of rejection. It is assumed that applicants intend for the arguments presented above in the traversal of the §103 rejection over Okamoto in view of Klein to be applied here as well.

In response, the examiner does the same. The rejection is maintained.

*

Claims 2-5, 7, 8 are rejected under 35 U.S.C. §103 as being unpatentable over Klein

(U.S. Patent 5,039,609) in view of Steudle (U.S. Patent 5,011,826).

As indicated, Klein teaches that peptides can be used in a dialysis solution. Also disclosed (col 12, line 40+) is that the peptides can be combined with another "osmotically balanced aqueous solution...". Klein does not single out glucose for this purpose. Steudle teaches (col 4, lines 51-59) that glucose can be combined with peptides in a peritoneal dialysis solution. Also stated (col 3, line 25+) is that attempting to sterilize a solution containing peptides and reducing sugars can result in a Maillard reaction.

In response to this ground of rejection, it is argued (response, 5/9/03) that the mere mention of a combination of peptides with glucose in the same sentence is not a sufficient basis for an obviousness rejection. While it is true that a §103 rejection should not be based *solely* on this one sentence, it does remain the case that this one sentence is an important part of the basis of the rejection. In the response (filed 5/9/03) it is argued that Klein is deficient with respect to the polypeptide feature of the claimed invention. However, no such deficiency has been identified, and none is evident. It is also argued that Steudle does not provide specific information as to which peptides should be selected.

In response, it is noted first that none of claims 2-4 or 7 imposes any limitations on the structure, composition, or molecular weight of the peptides. As for claims 5 and 8, these limitations are disclosed in Klein. It is also argued that Steudle does not define the circumstances under which peptides should be mixed with glucose. However, the instant

claims also do not define this. Steudle provides the suggestion to combine glucose and peptides. Nowhere in Steudle is there a statement that this particular teaching should be disregarded; moreover, no argument has been provided in the response (filed 5/9/03) as to why this teaching should be disregarded. In the response filed 5/9/03, it is argued that the solutions disclosed in Steudle require the presence of galactose. While this may be true, the instant claims do not exclude galactose. The instant claims would encompass, for example, solutions in which the ratio of galactose to glucose is 100:1. Thus, a peritoneal dialysis solution resulting from the teachings of Klein and Steudle is not distinguished from that claimed because of the presence of galactose.

The rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

D. Lukton 6/16/03

Christopher S. F. Low
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